

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

UNITED STATES OF AMERICA,

v.

ROBERT MENENDEZ

and

SALOMON MELGEN,

Defendants.

Crim. No. 2:15-cr-00155

Hon. William H. Walls

**DEFENDANTS' MOTION TO DISMISS THE INDICTMENT DUE TO THE
PROSECUTION PROVIDING FALSE TESTIMONY TO THE GRAND JURY AND
COMPROMISING THE GRAND JURY'S INDEPENDENCE**

(Motion to Dismiss No. 3)

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INTRODUCTION

Whether the grand jury provides the protections the Founders intended or not, it certainly cannot serve as a check on the government's power or promote the rights of individuals if the grand jury process is abused. (See MTD No. 4 (describing role of the grand jury).) From the discovery provided in this case, it appears the grand jury was prevented from playing any role other than as a rubber stamp for prosecutors determined to bring the charges in this case.

To protect the independence of the grand jury and its ability to make an informed decision on questions of probable cause, both the courts and the U.S. Department of Justice ("DOJ") itself have placed limits on how evidence can be presented to the grand jury. The prosecution has considerable leeway in presenting evidence to the grand jury, but its discretion is not unfettered. Ordinarily and ideally, evidence comes to the grand jury through witnesses with first-hand knowledge. As a matter of law, hearsay and the summary testimony of a case agent are permitted, but the use of both kinds of evidence is disfavored by the courts.

The prosecution of Defendants turns heavily upon a handful of meetings and telephone calls that Senator Menendez had with members of the Executive Branch. The Senator had a meeting with Secretary of Health and Human Services ("HHS") Kathleen Sebelius, which was attended by seven people. The Senator also met with and had a follow-up phone call with Marilyn Tavenner, Acting Administrator of the Centers for Medicare & Medicaid Services ("CMS") within HHS. There were at least four witnesses to those communications. Rather than call those witnesses to the grand jury, however, the prosecution had them interviewed by the FBI and then had a case agent testify as to what he, or his colleagues, said they learned from those individuals.

Not only was this an excessive (and, therefore, disallowed) use of hearsay through a case agent, but its use was made far worse by the way the testimony was elicited from the case agent. It was not as if, instead of calling the actual witnesses, the prosecution had the case agent recite what a witness had said. Instead, it was the prosecutor who really did the testifying, making long summaries of what the prosecutor claimed the case agent had learned (not surprisingly in a leading fashion that conformed to the prosecution's theory of the case) and then asking the case agent to confirm that was true. The actual testimony from the case agent-witness was typically just a one word answer of "yes" to confirm what was in essence the prosecutor's testimony. Were this technique not problem enough, a comparison of what the prosecutor said, the agent's affirmation and the actual interview of the witnesses indicates that the government provided a rendition of the interviews that was not accurate, meaning the grand jury was given incorrect testimony under oath. The attached Appendix (Ex. A) collects some of the notable examples discussed in this Motion concerning how the agent's testimony contradicts the government's own records of witness interviews. Based on this improper conduct inside the grand jury, the Court must dismiss the Indictment.

ARGUMENT

I. THE PROSECUTION'S PRESENTATION OF EVIDENCE TO THE GRAND JURY IS SUBJECT TO LIMITS

While the prosecution has wide latitude in how it presents evidence to the grand jury, there are limits to what it can do. "A prosecutor should of course inform a grand jury of any substantial evidence of which the prosecutor is aware that negates an accused's guilt, and should respond candidly to a grand jury's inquiries." United States v. Bari, 750 F.2d 1169, 1176 (2d Cir. 1984) (internal citation omitted). "Courts have also held that a prosecutor may not make statements or argue in a manner calculated to inflame the grand jury unfairly against an

accused.” United States v. Hogan, 712 F.2d 757, 759 (2d Cir. 1983) (citing United States v. Serubo, 604 F.2d 807, 1818 (3d Cir. 1979)). Dismissal may be warranted “where the prosecutor’s conduct amounts to a knowing or reckless misleading of the grand jury as to an essential fact.” Id. (affirming dismissal of indictment for soliciting false testimony).¹

While it is true that the prosecution can introduce hearsay to the grand jury, “extensive reliance on hearsay testimony is disfavored.” Hogan, 712 F.2d at 761.

More particularly, the government prosecutor, in presenting hearsay evidence to the grand jury, must not deceive the jurors as to the quality of the testimony they hear. Heavy reliance on secondary evidence is disfavored precisely because it is not first-rate proof. It should not be used without cogent reason, and never passed off to the grand jurors as quality proof when it is not.

Id. “[E]xcessive use of hearsay evidence in a grand jury proceeding may violate the defendant’s Fifth Amendment rights. . . . The grand jury may not become a ‘rubber stamp endorsing the

¹ “Although deliberate introduction of perjured testimony is perhaps the most flagrant example of misconduct, other prosecutorial behavior, even if unintentional, can also cause improper influence and usurpation of the grand jury’s role.” United States v. Samango, 607 F.2d 877, 882 (9th Cir. 1979); see Hogan, 712 F.2d at 759 (“In fact the gain in prosecutors’ influence over grand juries is all the more reason to insist that these limitations be observed strictly.”); United States v. Udziela, 671 F.2d 995, 998 (7th Cir. 1982) (“[I]n cases where over-zealous prosecutors have manipulated a grand jury by willfully misleading it or knowingly presenting false evidence, courts have not hesitated to exercise their power to dismiss indictments.”); see also Serubo, 604 F.2d at 817 (“[T]he costs of continued unchecked prosecutorial misconduct are also substantial. This is particularly so before the grand jury, where the prosecutor operates without the check of a judge or a trained legal adversary, and virtually immune from public scrutiny. The prosecutor’s abuse of his special relationship to the grand jury poses an enormous risk to defendants as well. For while in theory a trial provides the defendant with a full opportunity to contest and disprove the charges against him, in practice, the handing up of an indictment will often have a devastating personal and professional impact that a later dismissal or acquittal can never undo. Where the potential for abuse is so great, and the consequences of a mistaken indictment so serious, the ethical responsibilities of the prosecutor, and the obligation of the judiciary to protect against even the appearance of unfairness, are correspondingly heightened.”); United States v. Basurta, 497 F.2d 781, 785 (9th Cir. 1974) (“Today, the grand jury relies upon the prosecutor to initiate and prepare criminal cases and investigate which come before it. The prosecutor is present while the grand jury hears testimony; he calls and questions the witnesses and draws the indictment. With that great power and authority there is a correlative duty, and that is not to permit a person to stand trial when he knows that perjury permeates the indictment.”).

wishes of a prosecutor as a result of the needless presentation of hearsay testimony in grand jury proceedings.” United States v. Flomenhoft, 714 F.2d 708, 712 (7th Cir. 1983) (quoting United States v. Gallo, 394 F. Supp. 310, 314 (D. Conn. 1975)). The permissible use of hearsay requires “that the prosecutor does not deceive grand jurors as to ‘the shoddy merchandise they are getting so that they can seek something better if they wish.’” United States v. Estepa, 471 F.2d 1132, 1137 (2d Cir. 1972 (Friendly, J.) (internal citation omitted). The prosecutor has an “affirmative duty . . . to enlighten the grand jurors as to the hearsay quality of the evidence they were receiving.” Gallo, 394 F. Supp. at 315. To avoid misleading the grand jury, prosecutors should inform the grand jury that it has “a right to demand live witnesses.” Bari, 750 F.2d at 1177.

Although DOJ disagrees with the Estepa rule, it counsels its prosecutors to avoid running afoul of it. DOJ’s own guidance directs its attorneys to

avoid application of the Estepa rule by informing the grand jury of the hearsay nature of the testimony it is hearing and by offering to present eyewitness testimony if necessary. Further, when transcripts from a prior grand jury are presented to a new grand jury, the grand jurors should be advised of the hearsay nature of the transcripts and should be given the opportunity to recall any witnesses.

DOJ, Grand Jury Manual IV-13 (Nov. 1991); see id. IV-20 (“For example, in those jurisdictions that follow Estepa, the attorney should explain the hearsay nature of the prior transcript and should advise that live witnesses will be called if desired.”); id. IV-104 (“For example, in those jurisdictions that follow Estepa, the grand jurors should be informed whenever they are receiving hearsay evidence and should be instructed that they have the right to hear live witnesses.”);² DOJ, U.S. Attorneys Manual 9-11.232 (May 2012) (“Each United States Attorney should be

² The Third Circuit follows Estepa. United States v. Wander, 601 F.2d 1251, 1260 (3d Cir. 1979), see United States v. Ismaili, 828 F.2d 153, 164 (3d Cir. 1987).

assured that hearsay evidence presented to the grand jury will be presented on its merits so that the jurors are not misled into believing that the witness is giving his or her personal account.”).

Similarly, although DOJ does not believe it is constitutionally required to do so,

It is the policy of the Department of Justice, however, that when a prosecutor conducting a grand jury inquiry is personally aware of substantial evidence that directly negates the guilt of a subject of the investigation, the prosecutor must present or otherwise disclose such evidence to the grand jury before seeking an indictment against such a person.

U.S. Attorneys Manual 9-11.233.

Even though DOJ maintains that dismissal is not required where evidence is presented to a grand jury in violation of the Constitution, including the Speech or Debate Clause,

[n]onetheless, the Department has established a more exacting standard for its attorneys as follows: “A prosecutor should not present to the grand jury for use against a person whose constitutional rights clearly have been violated evidence which the prosecutor personally knows was obtained as a direct result of the constitutional violation.”

Grand Jury Manual IV-34 (quoting DOJ, U.S. Attorneys Manual 9-11.233).

A defendant’s right to an independent and informed grand jury is a substantial right and it can only be protected by dismissing an improperly obtained indictment. “While the prejudice to defendants is great, the court’s decision to dismiss the indictment is not prejudicial to the government; it may now take the case to another grand jury and start with a clean slate.” United States v. Breslin, 916 F. Supp. 438, 446 (E.D. Pa. 1996). As explained below, that right and numerous limits on prosecutorial misconduct addressed above were violated in this case.

II. THE PROSECUTION KNOWINGLY PRESENTED FALSE TESTIMONY TO THE GRAND JURY THROUGH ITS CASE AGENT

The crux of the prosecution’s case against Defendants is its claim that there was a corrupt agreement between Senator Menendez and Dr. Melgen, whereby Dr. Melgen allegedly gave Senator Menendez things of value in exchange for the Senator’s advocacy on Dr. Melgen’s

behalf before the Executive Branch. The prosecution has no direct evidence that there ever was such an agreement (because it did not exist), or what was specifically agreed to in that purported agreement. Rather, the prosecutors merely allege that Dr. Melgen gave gifts to his close friend Senator Menendez, and they are hoping to show that Senator Menendez later advocated on Dr. Melgen's behalf. The prosecutors will then ask the jury to infer, in the absence of any direct evidence whatsoever, that there must have been some *quid pro quo* linking these events together.

Among the flaws in this theory is that several of the key meetings in which the prosecution alleges Senator Menendez advocated to the Executive Branch on behalf of Dr. Melgen had a purpose different from what was portrayed by the prosecutors. Senator Menendez certainly learned of an issue involving the vagueness and potential inconsistencies in CMS's Medicare reimbursement policies as a result of Dr. Melgen's billing dispute with CMS. But the Senator's meetings with Secretary Sebelius and Administrator Tavenner concerned clarifying the policy as a general matter, and he did not ask either to intervene in Dr. Melgen's particular case. This is a distinction with a very important difference.

In an effort to make those meetings appear to the grand jury to be about Dr. Melgen, the prosecutors did not call the people who were present at those meetings to testify before the grand jury. Instead, they asked a case agent, eager to say "yes," to confirm that the prosecutors were right. In addition, they also erroneously suggested to the jury that they could not call these witnesses and hear the testimony for themselves. (*Infra* at 23-25.) And an analysis of the interviews and testimony demonstrate that the inflated claims they made to the jury did not jibe with what they knew to be true. And they did not just misspeak a little bit. In testifying about what the agent learned of the Tavenner and Sebelius meetings from those who were there, the agent provided a far different, and often contradictory, version of those events than what the FBI

302s reveal the agent actually was told by those witnesses. This presentation of false and inaccurate testimony requires the dismissal of the Indictment.

A. The Tavenner Meeting

Prior to the June 7, 2012 meeting with Tavenner, Senator Menendez had a call with Jonathan Blum at HHS on July 27, 2009. (Indict. ¶ 169.) Blum told the FBI that “MENENDEZ’ position was that the policy was wrong and unclear and that BLUM could not defend the policy. BLUM could not recall whether anyone mentioned a specific doctor’s name.” (Blum 2/13/13 FBI 302 at 3.) The FBI agent’s field notes reflect that, at this point, Blum indicated he was “not sure if [he] knew Melgen’s name.” (*Id.* at page 3 of attachment.) Although Blum understood that Dr. Melgen’s case is what brought the issue to Senator Menendez’s attention, Blum did not think Senator Menendez was asking him to intervene in Dr. Melgen’s case. (*Id.* at 4 (“BLUM did not think MENENDEZ was asking BLUM to interfere with the due process of CMS’ procedure.”).) While the impact of the policy issue may have been felt by Dr. Melgen, Blum told the FBI that Senator Menendez “talk[ed] about policy in general.” (*Id.* at page 5 of attachment). Rather, Blum believed the Senator was asking him “to clarify the policy, to make sure that this pattern of billing was permitted. MENENDEZ was focused on the policy.” (*Id.* at 4.) Blum recognized that “[a] change or clarification of the policy to allow such billing processes would impact MELGEN’s appeal,”³ but he did not believe the Senator was asking him to interfere directly in Dr. Melgen’s case. (*Id.* at 4-5.)

³ Dr. Melgen’s billing dispute with CMS was being appealed through an administrative adjudicative process. Any clarification of the policy going forward would not directly impact how the policy was applied previously to Dr. Melgen or any other doctor. Nevertheless, a clarification of the policy may have been indirectly helpful to Dr. Melgen in his appeal, as an acknowledgment that the prior policy was unclear or, as a matter of equity, he could argue that he should not be punished for what he did under the old policy when the same conduct would

Elizabeth Engel at HHS had helped set up that call and she participated in it. She recalled it as a policy call: “The issue dealt with the labelling of a particular drug or a dosing issue; how many doses were there per unit of the drug.” (Engel 4/15/13 FBI 302 at 2.) She recalled knowing that the matter concerned a doctor in South Florida, but she could not recall when she learned that, and there is no indication from her statement or Blum’s that Dr. Melgen’s name came up on the call. (Id.)

Later, on June 7, 2012, Senator Menendez met with Tavenner. (Indict. ¶ 200.) Maria Martino worked at CMS and she told the FBI that she initiated the meeting with Senator Menendez to help facilitate Tavenner’s confirmation by the Senate. (Martino 2/13/13 FBI 302 at 2; see Barnard 8/13/14 Tr. at 53 (explaining the meeting was part of the “nomination process”).) Blum prepared Tavenner for this meeting. (Blum 2/13/13 FBI 302 at 7.) Martino, Aryana Khalid (another CMS staffer) and Michael Barnard, Senator Menendez’s policy advisor, also attended this meeting.

The problem here begins with the fact that, with the exception of Barnard, the prosecution did not call any witness before the grand jury who was actually present at the

now be permitted under the new policy. Of course, even if CMS had changed the policy as Senator Menendez had suggested going forward, that would not necessarily have meant that the outcome of Dr. Melgen’s appeal under the prior policy would have been any different. There was nothing HHS or CMS could do that would interfere with Dr. Melgen’s pending case. Given that Dr. Melgen’s case is in a separate administrative proceeding, Blum explained “[t]he case involving DR. SALOMON MELGEN is outside the purview of CMS.” (Blum 2/22/13 FBI 302 at 1.) Instead, the matter was before an Administrative Law Judge (“ALJ”) who “operates independently from CMS. . . . CMS, by law, does not adjudicate claims.” (Id. at 2.) An appeal from an ALJ would go to “the Medicare Appeals Council (MAC) – which is the highest level of administrative appeal. . . . [T]he CMS Administrator does not have the authority to overrule a MAC decision. If the provider loses its MAC appeal, its next step is District Court.” (Blum 3/7/13 FBI 302, attachment to Blum from OL of 8/2/12 at 2; see Tavenner 2/13/13 FBI 302 at 5 (noting the adjudicative process was independent and she was never asked to send any letters on Dr. Melgen’s behalf).)

meeting; not Tavenner, not Khalid and not Martino. Instead, the prosecution called the case agent, Sheehy, and asked him what he learned from them. Prosecutor Koski leadingly asked: “Did Marilyn Tavenner confirm that during this meeting, Dr. Melgen [sic] was advocating on behalf of Dr. Melgen and his Medicare dispute?” (Sheehy 5/7/14 Tr. at 58.) Apparently, so ready (or prepared) to agree with anything the prosecutor said, Agent Sheehy simply answered, “Yes,” even though Mr. Koski had misspoken and claimed it was Dr. Melgen attending and advocating for himself at this meeting, which he did not attend.⁴

Given the centrality of Senator Menendez’s alleged official actions to the prosecution’s theory of the case, it was important to the prosecution for the grand jury to hear that Tavenner had said that, at this meeting, Senator Menendez “was advocating on behalf of Dr. Melgen.” (*Id.*) They also knew that if the grand jury was going to hear those words, Mr. Koski and Agent Sheehy would have to put those words into Tavenner’s mouth because she had not said them. The testimony of those who were present also would confirm that this meeting was the sort of policy discussion that is immunized by the Speech or Debate Clause.⁵ These two reasons can

⁴ Mr. Koski solicited almost identical testimony from Agent Sheehy stating that Senator Menendez was “advocat[ing]” on behalf of Dr. Melgen to Blum in a telephone conversation, despite evidence to the contrary that it was a policy discussion.

Q: And did one of your colleagues have an opportunity to interview Jonathan Blum?

A: Yes.

Q: And did Jonathan Blum confirm during the interview that the purpose of this call that Senator Menendez initiated, that his office initiated, was to advocate on behalf of Dr. Melgen?

A: Yes.

(Sheehy 5/7/14 Tr. at 57-58.)

⁵ In addressing matters that are protected by the Speech or Debate Clause in this Motion, Senator Menendez is not waiving the protections of the Clause at trial. (See, e.g., United States v. Johnson, 383 U.S. 169 (1966); In re Grand Jury, 587 F.2d 589, 597-98 (3d Cir. 1978); see also MTD Nos. 1-2 (Speech or Debate Clause).)

explain why the prosecution did not call Tavenner or anyone else from HHS as a witness before the grand jury.

Rather than say that Senator Menendez was advocating on behalf of Dr. Melgen, the FBI 302 summarizing her interview claims that “TAVENNER did not recall MENENZEZ [sic] specifically mentioning MELGEN’s name.” (Tavenner 2/13/13 FBI 302 at 3.) But as damaging as that is for the prosecution’s claim that she said the meeting was about advocacy for Dr. Melgen, the agent’s actual notes were even more definitive in stating the opposite. Tavenner said they did “not specifically discuss Melgen,” and she at least twice noted that she could not remember if his name even came up. (Id. attachment at 3-5.) Instead, Tavenner explained the meeting was exactly what Blum and her staff had led her to expect. Tavenner told the FBI that she and the Senator “debated policy.” (Tavenner 2/13/13 FBI 302 at 3.) Senator Menendez argued that CMS was acting “inconsistently and its policy was not clear,” and he wanted her “to change CMS’ policy.” (Id.) Advocating for a clearer policy where an individual or a number of people might be affected, is different than what the prosecution led the agent to say – he was “advocating on behalf of Dr. Melgen.”

The prosecution also did not call the other HHS staff who were present (again perhaps because the prosecution knew they would not testify that Tavenner said that Senator Menendez was advocating on behalf of Dr. Melgen either). Khalid told the FBI the same thing as Tavenner. (Khalid 2/13/13 FBI 302 at 1.) She explained that Senator Menendez was arguing that CMS’ guidance was “in conflict” and inconsistencies in the policy were discussed in detail. (Id. at 2.) The FBI 302 states: “KHALID did not recall MENENDEZ bringing up the name of the person who was effected [sic] by the policy.” (Id.) Likewise, Martino explained that she knew going into the meeting that the Senator has a “policy issue and MENENDEZ thought the program

instructions were confusing for doctors.” (Martino 2/13/13 FBI 302 at 2.) At the meeting, she said Senator Menendez did argue CMS’ “manuals were confusing and it looked like CMS changed the policy.” (*Id.*) She said she thought “MENENDEZ just wanted to understand the policy and wanted clarification” – the sort of information gathering that is immunized by the Speech or Debate Clause. (*Id.* at 2-3.)⁶ There is no mention in her FBI 302 of Dr. Melgen’s name coming up at this meeting.

The only other person at the meeting besides Senator Menendez was Barnard, who repeatedly told the prosecutors that their theory of that meeting was dead wrong. After Mr. Koski asked him about the Senator’s supposed advocacy for Dr. Melgen at that meeting, Barnard testified: “Your characterization was that the meeting was called to discuss Dr. Melgen, when in fact that was not the case.” (Barnard 8/13/14 Tr. at 55 (emphasis added).)⁷ Like every other first-hand account, Barnard repeatedly said that Dr. Melgen’s name was never mentioned because the meeting was about the overall policy and not his case. (*Id.* at 55-56.)

⁶ These Speech or Debate Clause issues are thoroughly addressed in MTD No. 1 at 4-7.

⁷ This was the second time Barnard told Mr. Koski he was wrong. Here was the first time:

Q: “Senator Menendez had meetings with Marilyn Tavenner, who at the time was the Acting Administrator of CMS, in order to advocate on behalf of Dr. Melgen --

A. No.

Q. -- in his \$8.9 million Medicare dispute. Isn’t that right?

A. That is incorrect.”

(Barnard 8/13/14 Tr. at 53; see also *id.* at 58 (explaining that if Dr. Melgen’s counsel thought the meeting would be to advocate on Dr. Melgen’s behalf, his assumption was wrong.) Later, Mr. Koski again asked: “Mr. Barnard, what was the purpose of Senator Menendez’s June 2012 meeting with Marilyn Tavenner?,” and Barnard answered: “The consideration of her nomination.” (Barnard 11/12/14 Tr. at 40; see *id.* at 45, 50 (same).)

The only mention of advocacy in the FBI 302 of Tavenner was in a context that was far more abstract. After discussing the meeting with Senator Menendez, Tavenner was asked about meetings with Members of Congress generally. She said she had been called to meet with a Member more than a dozen times, sometimes the constituent is present, and sometimes she is asked to help. (Tavenner 2/13/13 FBI 302 at 4.) She also explained that it is not uncommon for a Member to advocate on behalf of a constituent. (Id.) The FBI 302 then makes a statement that distorts what is recorded in the agent's notes. The FBI 302 says: "TAVENNER thought that it was unusual that MENENDEZ was advocating for someone who was not his (MENENDEZ') constituent." (Id.) But the agent's actual field notes reflect that Tavenner was still just speaking generally, and not with respect to Senator Menendez in particular. (Id. attachment at 4.)

The notes only address Tavenner's generic statements about the ordinary process of meeting with members of Congress. The notes state "– not uncommon to advocate for constituent – thought unusual that advocate for non-constituent." (Id.) There is no mention of Senator Menendez at all in this part of the discussion. Moreover, it is clear from the preceding section of the agent's notes that Tavenner certainly was not suggesting that Senator Menendez was advocating on behalf of Dr. Melgen at their meeting. As noted above, the FBI 302 report and the agent's field notes reflect that Tavenner said Dr. Melgen's situation was not discussed and she was not even sure if his name was mentioned, so Tavenner did not regard the meeting as about advocacy for Dr. Melgen.

Consequently, Mr. Koski and Agent Sheehy knew (or should have known) there was no basis for their claim to the grand jury that Tavenner said Senator Menendez was "advocating on behalf of Dr. Melgen" at that meeting. (Sheehy 5/7/14 Tr. at 58.) Moreover, they certainly were aware of considerable evidence – statements from everyone who was there – that no mention of

Dr. Melgen was even made at that meeting. To avoid misleading the grand jury, that information should not have been omitted from Agent Sheehy's testimony. Moreover, DOJ's own policy required that such evidence be provided to the grand jury. U.S. Attorneys Manual 9-11.233.

B. The Tavenner Follow-Up Call

On July 2, 2012, there was a follow-up call between Senator Menendez and Tavenner. (Indict. ¶ 204.) Also present on that call were Martino and Barnard. Again, the prosecution did not call Tavenner or Martino to address what was said at that meeting. Once again, Mr. Koski had Agent Sheehy testify as to what he was told about that meeting. Mr. Koski asked Agent Sheehy if there was a follow-up call "between [Tavenner] and Senator Menendez relating to this Dr. Melgen Medicare issue?," and Agent Sheehy again readily answered, "Yes." (Sheehy 5/7/14 Tr. at 59.) To clarify that the call did not go well, Mr. Koski reverted to his practice of stating the testimony he wanted and asking the case agent to confirm he was correct. Mr. Koski asked: "Meaning specifically that Marilyn Tavenner confirmed that she told Senator Menendez that there was nothing they could do, they were not going to change their policy, they weren't going to change their decision with respect to Dr. Melgen and his Medicare dispute?" (Id.) Agent Sheehy answered: "Correct. And they wouldn't allow the appeal process to go forward." (Id.)

Again, the testimony elicited by Mr. Koski and Agent Sheehy was not accurate. This call was not "relating to this Dr. Melgen Medicare issue," and Tavenner had not "confirmed that she told Senator Menendez that there was nothing they could do, . . . they weren't going to change their decision with respect to Dr. Melgen and his Medicare dispute." (Id.) There was no discussion at all about "their decision with respect to Dr. Melgen," or whether to "change" their decision. And there was no discussion whatsoever of the "appeals process" at all, much less of them not allowing it "to go forward." (Id.)

The FBI 302 reports Tavenner said that it was a short call about policy, which lasted just 2 to 3 minutes. (Tavenner 2/13/13 FBI 302 at 4.) She told Senator Menendez that she “looked at the policy regarding billing for vials used by multiple patients and the policy stood.” (Id.) This discussion of policy, with no mention of Dr. Melgen, is what Tavenner had anticipated before the call.⁸ Likewise, Martino told the FBI that she was on this call and Tavenner explained that for policy reasons – “for infection control reasons, the single use vial policy would not and had not changed. The call ended shortly thereafter.” (Martino 2/13/13 FBI 302 at 2.) Again, Martino makes no mention of Dr. Melgen or any appeal of a decision concerning him. (See also Khalid 2/13/13/ FBI 302 at 3 (noting Blum relayed to her that in the follow-up call with Senator Menendez, that Senator was told “CMS was not going to change its policy.”).)⁹ Consequently, Tavenner had not said the meeting related to Dr. Melgen, or to any decision CMS had made about him or any appeals process.

Agent Sheehy’s comment that “they wouldn’t allow the appeal process to go forward” appears to be completely made up. (Sheehy 5/7/14 Tr. at 59.) Not only is there no indication that Dr. Melgen’s case or the appeal process was even discussed on this call, but Tavenner certainly would not have said they would not allow the appeals process to go forward. Tavenner told the FBI “[t]he appeals process is conducted by an Administrative Law Judge (ALJ), which is an independent entity. The ALJ reports to HHS, not to CMS.” (Tavenner 2/13/13 at 5.) More than a year before Agent Sheehy testified, Blum already had explained to the prosecution that the

⁸ In setting up the call, Tavenner was advised “that the Senator would like to focus on the Medicare reimbursement policy.” (Blum 3/17/13 FBI 302, attachment 6/29/12 Note to Tavenner from Office of Legislation.) Her talking points in preparation for the meeting focused solely on the policy, with no mention of Dr. Melgen directly or indirectly. (Id.)

⁹ Barnard acknowledged being present on the call but refused to answer any questions about it, citing the Speech or Debate Clause. (Barnard 8/13/14 Tr. at 56.)

adjudicative side was independent, and neither HHS nor CMS could interfere with it. (Supra at 7-8 n.3.) There is no indication that the appeals process was not allowed to run its course or that Tavenner or anyone else at HHS or CMS had tried to stop it. This was simply testimony made up for the grand jury suggesting, without any basis, that Tavenner found Senator Menendez's purported advocacy for Dr. Melgen so outrageous that she halted Dr. Melgen's appeal.¹⁰

C. The Sebelius Meeting

A meeting with Secretary Sebelius was held on August 2, 2012. (Indict. ¶215.) In attendance at the meeting with Secretary Sebelius were Senators Reid and Menendez, Jim Esquea (HHS), Kate Leone (Reid), Blum (HHS) and Barnard (Menendez). Again, the prosecutors did not call any of these witnesses before the grand jury, except Barnard.¹¹ Once again, the testimony about what occurred at this meeting would come through Mr. Koski saying what happened and Agent Sheehy agreeing with him. At the meeting with Secretary Sebelius, the case agent testified that "Senator Menendez made the arguments on behalf of Dr. Melgen, similar arguments that had previously been made to Jonathan Blum and Marilyn Tavenner." (Sheehy 5/7/14 Tr. at 65.) When asked: "Was it also clear that the meeting was about Dr. Melgen?" the case agent answered: "Perfectly clear. . . . It was all about Dr. Melgen, the meeting." (Id. at 66 (emphasis added).)

¹⁰ Mr. Koski knew the witness' testimony about Tavenner halting the appeal process was not true, but no effort was made to correct that testimony as he was required to do. As was noted in another case brought by this prosecutor's office, the prosecution has an obligation to correct the record. Report of Special Counsel, In re Special Proceedings (Stevens), Misc. No. 09-0198, Dkt. 84 at 19 (D.D.C. filed Mar. 13, 2012) ("[The prosecutor] knew the testimony was false and knew that he had an obligation under the Supreme Court's decision in Napue v. Illinois, 360 U.S. 264 (1959) to correct that testimony there and then, but he did not.").

¹¹ Barnard testified that he attended the meeting, but he refused to answer questions about it based on the Speech or Debate Clause. (Barnard 11/12/14 Tr. at 56, 60-61.) Leone apparently has not been interviewed by the FBI.

Later, Agent Sheehy gave similar testimony to the grand jury. Prosecutor Monique Abrishami asked him: “[D]id your investigation reveal that Senator Menendez met with HHS Secretary Sebelius and Senator Reid about Dr. Melgen’s Medicare billing dispute?,” and Agent Sheehy on cue answered succinctly, “Yes.” (Sheehy 4/1/15 Tr. at 23 (emphasis added).) Ms. Abrishami followed up by asking: “And did your investigation reveal that during that meeting Senator Menendez advocated on behalf of Dr. Melgen’s position in his Medicare billing dispute focusing on Dr. Melgen’s specific case and asserting that Dr. Melgen was being treated unfairly?,” and Agent Sheehy again answered succinctly, “Yes.” (*Id.* (emphasis added).)

Again, the testimony the prosecutors elicited from Agent Sheehy was not true. Agent Sheehy’s statement that Senator Menendez made arguments on behalf of Dr. Melgen that were similar to the arguments he previously raised with Blum and Tavenner simply compounded his prior erroneous testimony because, as noted above, there were no prior arguments on behalf of Dr. Melgen to Blum or Tavenner. The arguments before, and the arguments here, were about policy. And the prosecution knew that from multiple sources. It was not “[p]erfectly clear” that the meeting “was all about Dr. Melgen.” (Sheehy 5/7/14 Tr. at 66.) If the prosecution was going to have its case agent say what witnesses had told him, it should have had him read their actual statements into the record.

Agent Sheehy testified that he understood the conversation was essentially a debate between Senator Menendez and Blum, in which they did most of the talking. (Sheehy 5/7/14 Tr. at 65; *see id.* at 66 (“Senator Menendez was doing most of the talking”); Blum 2/13/13 FBI 302 at 6 (“MENENDEZ and BLUM did most of the talking during the meeting.”); Reid 4/28/13 FBI 302 at 3 (same).) In sharp contrast to Agent Sheehy’s testimony that it was “[p]erfectly clear” that the meeting “was all about Dr. Melgen,” Blum told the FBI that the “focus of the

conversation was on the policy, which REID and MENENDEZ said was vague. MENENDEZ and REID said that they (MENENDEZ and REID) were not there to talk about a particular case; they were there to talk about policy.” (Blum 2/13/13 FBI 302 at 5 (emphasis added).)¹² While Blum believed that Dr. Melgen’s situation is what brought the issue to Senator Menendez’s attention, “BLUM did not recall MELGEN being mentioned by name at the meeting.” (Id. at 6; see Blum 5/16/13 FBI 302 at 1 (again relaying that Senator Menendez raised at that meeting whether “CMS policy regarding Lucentis was inconsistent with how CMS handled” other matters; no mention of Dr. Melgen).) He explained, “MENENDEZ and REID advocated a change to CMS’ policy to allow the pattern of billing” (and, of course, such a change in policy is forward-looking). (Blum 2/13/13 FBI 302 at 5.) Blum also told the FBI that Senator Menendez indicated he would use his role on the Finance Committee to stay on top of the issue, and led him to expect that Blum “would have to answer questions about this policy” the next time he testified at a hearing before the Committee. (Id. at 6.) The prosecution may have sought to recast this conversation to be something other than what it actually was – a discussion about policy – to avoid running head on into the bar of the Speech or Debate Clause. (See MTD No. 1 at 8-12.)

Sebelius explained that she did not do much to prepare for the meeting, as Blum “would be able to discuss the Medicare issues.” (Sebelius 4/15/13 FBI 302 at 3.) Like Blum, Sebelius “could not recall whether MELGEN’s name specifically came up during the meeting.” She said they did focus on one example where they felt a “doctor was a victim of rule changes,” which

¹² Prior to the meeting, Blum received a memo from the Office of Legislation advising him of the subject of the meeting: “The issue is with Medicare payment of single-use vials of injectable prescription medicines and whether Medicare has ever allowed multiple billings when a drug in a single-use vial is used multiple times.” (Blum 3/7/13 FBI 302, attachment to Blum from OL of 8/2/12 at 1.) The memo did note that Senator Menendez has raised “the case of a Florida physician,” but the memo addressed the merits of the policy of multi-dosing. (Id.)

they viewed as “unfair treatment,” but they “spoke more broadly about how it was unfair to healthcare providers.” (Id.) In other words, and in contrast to Agent Sheehy’s mischaracterizing testimony, it was not “[p]erfectly clear” that the meeting “was all about Dr. Melgen;” it was “more broadly about . . . healthcare providers.” (Compare Sheehy 5/7/14 Tr. at 66, with Sebelius 4/15/13 FBI 302 at 3.) Sebelius said she “could not recall what MENENDEZ specifically wanted.” (Sebelius 4/15/13 FBI 302 at 5.) With respect to the specific example he had given, she did note that the dispute was in the “appeals process” and, due to its independence, “there was nothing SEBELIUS could have done, even if she (SEBELIUS) wished to intervene.” (Id. at 4.) (Nobody claims that Senator Menendez asked Sebelius to intervene in Dr. Melgen’s case either.)

Senator Reid told the FBI that his role was chiefly to set the meeting, and it was mostly Senator Menendez and Blum who spoke. (Reid 4/28/14 FBI 302 at 3 (“REID and SEBELIUS spoke very little during the course of the meeting.”).) “REID believed that MENENDEZ was making good points” on matters of policy, as we should not “throw away excess medicine.” (Id.) No one in attendance actually recalled Dr. Melgen’s name coming up, and Senator Reid made clear to the FBI that the discussion centered on clarifying the policy. (Id.)

Esquea also testified that the meeting was about policy: “MENENDEZ was focused on the policy and how the policy was applied. MENENDEZ said that there was confusion because CMS changed its policy. . . [and] anyone would find the rules confusing. ESQUEA did not recall whether MENENDEZ specifically mentioned MELGEN’s name.” (Esquea 4/15/13 FBI 302 at 5.) While Esquea disagreed with Senator Menendez, he believed “MENENDEZ thought that he (MENENDEZ) was making real policy points.” (Id. at 6.)

While HHS and CMS disagreed with Senator Menendez on what the policy should be, they did accept his argument that there was a need for the policy to be clarified. As Blum told

the FBI: “CMS has further clarified [its] policy (regarding vial splitting) in part because of this case and because of others that were similar.” (Blum 2/22/13 FBI 302 at 1; see Blum 3/7/13 FBI 302, attachment to Blum from OL of 8/2/12 at 3 (explaining “CMS clarified the policy”).) The fact that CMS clarified the policy demonstrates that Senator Menendez’s had raised a legitimate policy issue, and the Senator’s oversight activities (protected by the Speech or Debate Clause) were effective, at least in providing greater clarity going forward.

The prosecutors and Agent Sheehy had to know that it was not “[p]erfectly clear” that the meeting “was all about Dr. Melgen,” when that testimony was elicited. (Sheehy 5/7/14 Tr. at 66.) They also did not call as witnesses anyone who Agent Sheehy claimed provided the foundation for this testimony (it now being clear these witnesses did not say what the agent recounted). In addition, at a time the issue had been raised with the government, the prosecutors realized those witnesses would likely provide testimony about a policy dispute that would confirm the meeting was immunized by the Speech or Debate Clause. Many of the witnesses told the FBI explicitly that the meeting was about more than any individual case, and was about the policy more generally. That should have been disclosed. U.S. Attorneys Manual 9-11.233. By omitting those statements from his testimony, and instead relaying it was “[p]erfectly clear” that it “was all about Dr. Melgen,” Agent Sheehy’s testimony overreached and was not true. It is not difficult to imagine what the prosecution would have done if one of Senator Menendez’s staffers had provided the grand jury with such made-up testimony.¹³

¹³ Agent Sheehy also provided testimony that was incomplete and potentially misleading to the grand jury regarding a meeting Dr. Melgen had with Senators Harkin and Menendez. Agent Sheehy testified that at the meeting “Dr. Melgen explained his problems with CMS,” and argued that CMS’s policy against multi-dosing was wasteful. (Sheehy 5/7/14 Tr. at 48-49.) Agent Sheehy told the grand jury that Senator Harkin had a staff member reach out to CMS to get more information, but “his office did not advocate on behalf of Dr. Melgen.” (Id. at 49.) Agent

The Indictment must be dismissed. See, e.g., Hogan, 712 F.2d at 761-62 (ordering dismissal of indictment for “the DEA agent’s false testimony to the grand jury,” even if “the factual misstatements in the agent’s testimony may have been inadvertent”); Samango, 607 F.2d at 882 (dismissing indictment); Basurto, 497 F.2d at 785-787 (same); Gallo, 394 F. Supp. at 315 (same); see also United States v. Akel, 337 F. App’x. 843, 858 (11th Cir. 2009) (noting government’s knowing use of false testimony or failure to correct such testimony upon learning of it warrants dismissal).

III. THE PROSECUTION OVERRELIED ON ITS CASE AGENT AND HEARSAY

The heart of this case is the prosecution’s claim that Dr. Melgen gave things of value to Senator Menendez in exchange for the Senator advocating on Dr. Melgen’s behalf before the Executive Branch, but the prosecution never called even a single member of the Executive Branch to testify before the grand jury. Even though there were numerous witnesses to Senator Menendez’s communications with the Executive Branch, including those with Sebelius and Tavenner, the prosecution did not call any witnesses to those meetings to testify except those who were on Senator Menendez’s staff. Even then, their testimony was limited about these meetings because they invoked their constitutional privilege not to testify based on the Speech or Debate Clause. Consequently, the only meaningful testimony the grand jury heard about these communications was hearsay that came in through a case agent, who had no first-hand

Sheehy explained that Senator Harkin’s staffer, Nick Bath, looked into these policy issues and concluded that CMS was right and Dr. Melgen was wrong. (Id. at 49-52.) Agent Sheehy’s testimony may have misled the jury into believing that Senator Harkin had refused a request from Dr. Melgen to assist him. Although Agent Sheehy’s interview notes with Senator Harkin reflect that “HARKIN does not recall MELGEN ever specifically asking him to do anything and HARKIN never did do anything on MELGEN’s behalf,” that information was not shared with the grand jury. (Harkin 5/1/14 FBI 302 at 2.)

knowledge, and who for the most part was simply agreeing with prosecutors who were really the ones testifying through their leading questions.

If any meaningful limits do exist on what the prosecution can do before the grand jury – and the case law and DOJ’s own guidance confirm that such limits do exist – then those limits certainly were crossed here. The prosecution’s use of a single case agent witness to recount these conversations, when the prosecution could have called any number of witnesses who were present for those discussions and who the case agent had interviewed, is improper. In similar circumstances, the Second Circuit explained:

As we see it, there is a great deal to criticize in the government’s handling of this grand jury proceeding. The single-witness policy routinely relies on hearsay, producing “evidence which appears smooth, well integrated and consistent,” making even weak cases appear strong. It also “prevents the defendant from utilizing grand jury testimony in cross-examining witnesses who will testify at trial.”

United States v. Brito, 907 F.2d 392, 395 (2d Cir. 1990) (quoting United States v. Arcuri, 282 F. Supp. 347, 349 (E.D.N.Y. 1968) (Weinstein, J.). The Second Circuit also has emphasized

excessive use of hearsay in the presentation of government cases to grand juries tends to destroy the historical function of grand juries in assessing the likelihood of prosecutorial success and tends to destroy the protection from unwarranted prosecutions that grand juries are supposed to afford to the innocent. Hearsay evidence should only be used when direct testimony is unavailable or when it is demonstrably inconvenient to summon witnesses able to testify to facts from personal knowledge.

United States v. Umans, 368 F.2d 725, 730 (2d Cir. 1966); see Estepa, 471 F.2d at 1135 (Judge Friendly condemning the “casual attitude with respect to the presentation of evidence to a grand jury” through the reliance of a case agent, when better witnesses were available.)

That is certainly what happened here. At the Sebelius meeting, for example, there were seven people present, but they were not called as witnesses and there is no justifiable reason for that. See, e.g., United States v. Felton, 755 F. Supp. 72, 75-76 (S.D.N.Y. 1991) (explaining the court “repeatedly asked” prosecutors why they called only an agent who was not present to

testify before the grand jury about the circumstances of an arrest, when the three arresting officers were available, and expressing its “displeasure” with that practice and the concern it raised that this “misled the grand jury”) Instead, a case agent testified that he learned what happened from interviewing several of those who were present. When asked: “Was it also clear that the meeting was about Dr. Melgen?,” the case agent confirmed: “Perfectly clear. . . . It was all about Dr. Melgen, the meeting.” (Sheehy 5/7/14 Tr. at 66 (emphasis added).) That certainly “appears smooth well integrated and consistent” – even though nobody who was present at that meeting would have answered the question as Agent Sheehy had, even in response to the prosecutor’s leading question. As explained above, nobody who the FBI interviewed who attended that meeting could even recall Dr. Melgen’s name coming up, and they all said the meeting was about policy. (Supra at 16-18.) Had the prosecution called the people who were actually there and asked them the same question, it is utterly implausible that the grand jury would have been left with the same “perfectly clear” understanding of the meeting that the case agent – with no first-hand knowledge, relying exclusively on hearsay and the prosecutor’s leading questions – conveyed. While this would require the dismissal of the Indictment in its own right because the issue is so central to the case, dismissal is all the more required because the case agent’s testimony was “inaccurate.” United States v. Peralta, 763 F. Supp. 14, 21 (S.D.N.Y. 1991) (dismissing an indictment based on a case agent testifying in this manner, emphasizing that dismissal was especially required because the agent’s testimony was inaccurate) (emphasis in original). Compounding these errors further is the fact that it was really the prosecutors themselves who were doing most of the testifying through their leading questions, and that too is improper. See, e.g., Brito, 907 F.2d at 394 (complaining “the prosecutor, herself was the ‘true’ witness because the agent’s testimony was presented through

leading questions”); Samango, 607 F.2d at 883 (criticizing “testimony by the prosecutor in the form of questions” to a grand jury witness); see also Hogan, 712 F.2d at 760 (criticizing a prosecutor for “[m]aking himself an unsworn witness”).

In addition, there is no indication that the prosecution gave the grand jury any warning associated with the hearsay involved in the numerous read-backs of prior testimony or in the case agent relaying what others had told him (or, even more attenuated, had told other FBI agents who then told him) what was discussed at various meetings. Not only did the prosecution not caution the grand jurors as to the “shoddy nature” of the materials they were getting, or inform them they could subpoena live testimony, it does not appear there was any good reason not to call live witnesses. Hogan, 712 F.2d at 761; Samango, 607 F.2d at 882 (affirming dismissal where “[t]he prosecutor should have attempted to present live testimony”); Estepa, 471 F.2d at 1137.

IV. THE GRAND JURY WAS ERRONEOUSLY LED TO BELIEVE IT COULD NOT CALL LIVE WITNESSES

When the prosecution first called Agent Sheehy to the grand jury, it was for the purpose of providing read-backs of prior testimony to a grand jury that the prosecutors first convened in Florida. (Sheehy 2/26/14 Tr. at 2.) After the prior testimony of several witnesses was read back to the grand jury and the grand jury was preparing for yet another read back, a grand juror asked: “Can I ask you a question? Eventually are these people going to come here?” (Id. at 144.) Mr. Koski succinctly answered in just one word – “No.” (Id.) The grand juror responded by asking: “Never? Okay.” (Id.)

The grand juror clearly was under the misimpression that it was the prosecutors, and not the grand jury, who would decide whether live witnesses would be called before the grand jury. That misimpression was then confirmed by the prosecutor’s answer, which was simply “No,”

those witnesses would not be coming before the grand jury.¹⁴ The grand jury was left with the impression that “[n]ever” was going to happen. The correct answer, and the one required by the case law and DOJ’s own policy, would have been to tell the grand jury that they had the power to subpoena those witnesses, so that they could hear live testimony and ask them their own questions. The answer given by Mr. Koski is not only inconsistent with the case law, it is inconsistent with DOJ’s own guidance that “grand jurors should be informed whenever they are receiving hearsay evidence and should be instructed that they have the right to hear live witnesses.” Grand Jury Manual IV-104.

In United States v. Breslin, 916 F. Supp. 438 (E.D. Pa. 1996), the court dismissed an indictment because “[t]he prosecutor improperly led the jury to believe that it was not entitled to

¹⁴ Elsewhere, the prosecution misdirected the grand jury into believing that the prosecution was in control of the grand jury, and that it did not have the independence to make inquiries on their own. After testimony was elicited about Senator Menendez being involved in litigation and contributions to his legal defense fund, a grand juror had questions about both. (Sheehy 5/7/14 Tr. at 72-74.) Agent Sheehy explained that the litigation involved Senator Menendez in his capacity as a Senator, but refused to provide further explanation, stating “that is not part of . . . [t]he subject of that was not the subject of this.” (*Id.* at 73-74.) Of course, the grand jury can decide for itself what it wants to investigate. Agent Sheehy’s response told the jury that the prosecution will decide the scope of the grand jury’s investigation.

Later, a grand juror asked Agent Sheehy, “were you aware if other practitioners, I guess you would say other ophthalmologists who were engaging in this activity of multi-dosing and --” but Agent Sheehy interrupted and began to answer by saying, “[a]ctually, we have --,” and Mr. Koski stopped him. (*Id.* at 74.) Mr. Koski stated that he wanted to “clarify and narrow the scope of the question,” although a prosecutor has no right to “narrow” the grand jury’s inquiry, particularly of facts that may be helpful to an accused. (*Id.*) But Mr. Koski did not clarify or narrow any question about whether other doctors were multi-dosing. Instead, he asked a series of questions about there being a “separate investigation” of “Dr. Melgen for health care fraud,” and Agent Sheehy confirmed he was not part of that investigation. (*Id.*) Not only did Mr. Koski’s answer preclude the grand jury from going down a path of looking for potentially exculpatory evidence, his answer again told the jury that the prosecution decides what this grand jury would consider and what would be kept “separate.” The answer undermined the grand jury’s independence, and reinforced the flawed notion that the grand jury was the agent of the prosecutor; not the other way around. Moreover, Mr. Koski prejudiced Senator Menendez and especially Dr. Melgen by injecting the notion of a different Medicare fraud case into this inquiry.

request live witness testimony or that live witness testimony was unavailable.” Id. at 444. The prosecutor there told the grand jury that witnesses did not testify live because the prosecutor read them the testimony instead. Id. Mr. Koski telling the grand jury that “No,” those witnesses will not be coming to testify even more clearly signaled that live testimony would “[n]ever” be available. “The prosecutor should also have informed the jurors that [the witnesses were] available for live testimony in the event they wished to evaluate the credibility [their] credibility for themselves. . . .” Gallo, 394 F. Supp. at 315 (dismissing indictment).

Moreover, the problem here is too pervasive to be dismissed as harmless. There were extensive read-backs of prior testimony through the case agent. (Sheehy 2/26/14 Tr. at 3-8 (Ravido read-back); id. at 18-30 (Donovan read-back); id. at 30-55 (Butt read-back); id. at 55-78 (Nylund read-back); id. at 79-144 (Fernandez read-back); id. at 144-230 (Lopez-Leite read-back); Sheehy 4/9/14 Tr. at 3-57 (Buchyk read-back); Sheehy 4/30/14 Tr. at 3-38 (Polanco read-back); Sheehy 10/8/14 at 4-39 (Almeida read-back); Sheehy 3/11/15 Tr. at 68-91 (read-back of Talbot testimony).) The case agent also gave extensive hearsay testimony as to what he learned through interviews of others. ((Sheehy 4/9/14 Tr. at 59 (Buchyk); Sheehy 5/7/14 Tr. at 48 (Harkin); id. at 49 (Bath); id. at 54 (Sebelius); id. at 57 (Blum); id. at 58 (Tavenner).) If the grand jury had known of its ability to call witnesses, like Sebelius and Tavenner, and others who were present at key meetings, it may very well have done so, and it would have received a far different understanding of the facts than the prosecution presented. Given that the prosecution called numerous female acquaintances of Dr. Melgen so it could question them about every irrelevant detail of their relationship with him, the prosecution can hardly complain the grand jury did not have time to hear from first-hand witnesses to the events central to this case. By compromising the independence of the grand jury and its basic fact-finding ability, the grand

jury simply became a tool of the prosecution. Defendants' right to an independent and informed grand jury was violated, and the Indictment must be dismissed.

V. AGENT SHEEHY INACCURATELY SUMMARIZED IMPORTANT LEGAL ISSUES FOR THE GRAND JURY

During the grand jury proceeding, prosecutors presented the jurors with a lengthy proposed charged instrument that includes over 88 paragraphs dealing with Dr. Melgen's practice of repackaging or multi-dosing Lucentis and his dispute with CMS. To explain the law on the issue, prosecutors could have presented: (1) the United States Code, (2) Food and Drug Administration ("FDA") and CMS guidance, (3) decisions from U.S. Courts such as Hayes v. Sebelius, 589 F.3d 1279 (D.C. Cir. 2009), or (4) witnesses from the HHS Office of General Counsel or HHS Office of Inspector General. Instead, they elected to have Agent Sheehy inaccurately summarize the law in his testimony. That testimony neglected to present any of the four truthful and accurate sources of the law that were public information in the government's possession at the time of the testimony. As such, the prosecutors elected to present the grand jurors with a legally incorrect and bias summary of legal issues.

On May 7, 2014, Agent Sheehy testified before the grand jury related to Dr. Melgen's dispute with CMS over the billing of Lucentis. Mr. Koski asked Agent Sheehy the following:

Q: And are you aware of whether there are any FDA or CDC guidelines that either discourage or prohibit an ophthalmologist from using any of the overfill to treat multiple patients or from harvesting the excess amount of Lucentis in order to treat multiple patients?"

In response, Agent Sheehy testified unequivocally: "The guidelines prohibit that practice." (Sheehy 5/7/14 Tr. at 16.) As stated in MTD No. 1 at 14 n.11 this case does not involve the use of "overfill," because the drug manufacturer's labeling with each purchased vial of Lucentis

stated that the vials contained 0.2 mL of product, or 400% of the recommended standard dose of 0.05 mL.¹⁵

Mr. Koski proceeded with the following line of questioning:

Q: Agent Sheehy, are you also aware of whether Medicare has any reimbursement policy related to Lucentis, meaning, let me be more specific, if an ophthalmologist spends money to purchase a single vial of Lucentis, how much money is that ophthalmologist entitled to receive from Medicare based on that expense?

A: The ophthalmologist is entirely reimbursed for his expense. And in addition, a percentage above that is included. . . .

Q: And so if an ophthalmologist ignores the FDA and CDC guidelines and harvests the overfill of Lucentis to treat multiple patients, is that ophthalmologist – under the Medicare regulations, is that ophthalmologist entitled to be reimbursed for the additional costs of a vial of Lucentis?

A: Well, no. . . .

(Sheehy 5/7/14 Tr. at 16-17.) Agent Sheehy misstated the law in each one of his answers, as evidenced by the government's own investigation records, FDA and CMS guidelines, and established case law.¹⁶

First, FDA guidelines contradict Agent Sheehy's testimony that "[t]he guidelines prohibit that practice" of using overfill to treat multiple patients. As noted above (and in MTD No. 1 at

¹⁵ See Genentech, Inc., Lucentis - Highlights of Prescribing Information § 16 (June 2010) ("Each LUCENTIS carton, NDC 50242-080-01, contains a 0.2 mL fill of 10 mg/mL ranibizumab in a 2-cc glass vial"), http://www.genentech-access.com/sites/default/files/LUCENTIS_prescribing.pdf; see also Genentech, Inc., Lucentis - Highlights of Prescribing Information § 16 (June 2006) (same), <http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=6235>.

¹⁶ Additionally, Agent Sheehy simply misrepresented the CDC guidelines. They apply to reusing single-use syringes (*i.e.*, "needle-sharing"), which was never something that Dr. Melgen ever did, nor was it ever the topic of any discussion, as Dr. Melgen has openly and publicly stated his position on repackaging or multi-dosing Lucentis and Avastin. Simply put, Dr. Melgen has never re-used the same syringe twice, and this was never part of the administrative record before CMS because it never occurred.

14 n.11), this case does not actually concern “overfill.” In any event, the government’s own reports of interviews state matter-of-factly that in an interview with Camille Fall Blake in the Office of General Counsel at HHS, Ms. Blake stated “that she believed the FDA had been contacted regarding the potential issue of medical harm caused by reusing [*sic*] a single vial but that it was her understanding that the FDA will not support that claim.” (HHS OIG 3/15/13 Rep. at 3.) Indeed, in draft guidance issued by the FDA in February 2015, FDA states that physicians can multi-dose from single-use vials of Avastin and other ophthalmic drugs, even if the instructions state that the vial is “single-use” or that the physician must “discard” unused portions of the vial. See FDA, Draft Guidance Mixing, Diluting, Or Repackaging Biological Products Outside The Scope Of An Approved Biologics License Application Guidance For Industry (“FDA Draft Guidance”), 2015 WL 1735391, at *8 & n.15 (Feb. 2015). The FDA acknowledges that manufacturers’ instructions for ophthalmic drugs, such as “single dose or single use product, and related language,” do not preclude repackaging or multi-dosing. Id. at *8. Drugs such as Avastin and Lucentis that are “packaged in a single dose vial” may be “repackaged into multiple single dose syringes despite the fact that the label of the approved product states, ‘Single-use vial . . . Discard unused portion.’” Id. at *8 n.15 (discussing Avastin). This information could have been summarized for the grand jury, but was not disclosed.

Second, in contrast to Agent Sheehy’s erroneous testimony that multi-dosing is prohibited, CMS expressly permits and encourages the practice of multi-dosing for certain drugs, and its stated policy is to pay providers for this practice. Once again, the government’s own interviews with Ms. Blake and Tamara Forys of the HHS Office of Inspector General rebut Agent Sheehy’s statement of the law. According to the reports of their interviews, Ms. Blake and Ms. Forys clearly stated that prior to January 1, 2011, the precise period involving Dr.

Melgen's administrative appeal, "CMS approve[d] payment to providers for claims in which they billed for administering overfill to patients." (HHS OIG 3/15/13 Rep. at 3.) The report goes on to say "Ms. Blake said she spoke with John Warren (CMS/CMM) . . . and he stated that he did not recall a the [*sic*] conversation . . . in which he stated that CMS's position was that a physician should not bill for a cost in which they did not occur." (*Id.*) Indeed, when CMS published "Frequently Asked Questions" (FAQ) in March 2011, it posed the question "Will Medicare Part B pay for a drug from a single dose vial if it is administered to more than one beneficiary?" CMS's response acknowledged that the decision to multi-dose is a medical decision, and that it has no authority to regulate the practice of medicine. See id. (emphasis added). If CMS had concerns about physicians submitting Medicare claims for administered multi-dosed medicine from single-use vials, this was an obvious opportunity to say so. Instead, CMS's FAQ simply refers physicians to its policy on discarded drugs, which encourages physicians to administer drugs efficiently and recognizes multi-dosing as a legitimate practice. *Id.*; CMS, Medicare Claims Processing Manual (Pub. No. 100-04), Ch. 17, § 40, <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf>.

Furthermore, the Medicare Program Integrity Manual ("MPIM") (Pub. No. 100-08) authorizes regional Medicare contractors to issue Local Coverage Determinations ("LCDs") governing when items and services are "reasonable and necessary" and thus payable by Medicare. 42 U.S.C. § 1395y(l)(5). In July 2009, the regional contractor in Dr. Melgen's area, First Coast Service Options Inc., issued a document clarifying its drug coverage policy conceding that the original Lucentis LCD was not clear and acknowledging that Medicare would pay for every dose of multi-dosed Lucentis that a physician "chooses" to administer. Local

Coverage Article for J2778: Ranibizumab (Lucentis®) article clarification (A49317) at 2 (emphasis added). None of this information was presented by the prosecutors to the grand jury.

Finally, the law on Medicare payment for Lucentis was well known to the government, and intentionally mischaracterized by Agent Sheehy to inflame the grand jurors.. Agent Sheehy testified that (1) an ophthalmologist would be “entirely reimbursed” for a vial of Lucentis and “a percentage above that is included” and (2) that ophthalmologists are not entitled to be reimbursed by Medicare for the practice of multi-dosing. (Sheehy 5/7/14 Tr. at 17.) All affirmative sources of legal authority plainly contradict Agent Sheehy’s testimony and the prosecutors presentation.

The law on how drugs are billed to Medicare Part B is provided in 42 U.S.C. §§ 1395k(a)(1) and 1395y(a)(1)(A). As part of the Social Security Act (“SSA”), drugs administered by physicians to Medicare patients that are “reasonable and necessary” for the treatment of disease or defect are paid incident to a physician’s professional service. Id. § 1395x(s)(2)(A). CMS must pay for physician-administered drugs based on the lower of (1) a physician’s actual billed charge,¹⁷ or (2) 106% of the Average Sales Price (“ASP”) of the drug. 42 U.S.C. § 1395w-3a; 42 C.F.R. § 414.904(a). At all times relevant to this case, Dr. Melgen billed for each unit of Lucentis he administered at 106% of the ASP.

Pharmaceutical manufacturers report a drug’s “ASP” based on the price derived from nationwide sales, divided by the total number of “units” of such drug. 42 U.S.C. § 1395w-3a(c)(1). The ASP is updated quarterly, based upon the manufacturer’s aggregate data. Id. §

¹⁷ While not defined in the statute, “actual billed charge” has been interpreted by CMS to mean the amount “a doctor or supplier charges for a certain medical service or supply.” CMS, Glossary, “Actual Charge”, <http://www.cms.gov/apps/glossary/default.asp?Letter=A&Language=English>. This interpretation does not refer to or include any reference to the “cost” or “expense” of acquiring a drug. See id.

1395w-3a(c)(5)(B). Therefore, Medicare’s payment is based solely on the number of “dosage unit[s]” of a drug administered to treat a patient. Id. § 1395w-3a(b)(1); 42 C.F.R. § 414.904(a). The statutory price is paid per unit administered, and CMS has no authority to change that price. In Hays, the D.C. Circuit confirmed that CMS has no discretion to deviate from this payment framework when paying for drugs under Medicare. Hays held that Medicare payments to physicians for drugs must be calculated in the manner dictated by Congress. Id. at 1283. Under that framework, the Secretary can “make only a binary choice: either an item or service is reasonable and necessary, in which case it may be covered at the statutory rate, or it is unreasonable or unnecessary, in which case it may not be covered at all.” Id. at 1283 (emphasis added). Therefore, CMS is bound by the statutory per-unit payment framework. Id. at 1283. It is undisputed that Dr. Melgen only billed for what the patients actually received; typically, a standard dose of Lucentis was five units, and he was paid per five-unit dose, consistent with the ASP statutory framework. But despite the clear statutory language and case law supporting that language, the prosecutors and Agent Sheehy intentionally and repeatedly presented the grand jury with an inaccurate summary of the law.¹⁸

¹⁸ Q: So it looks like in this argument Dr. Melgen and his team are conflating or confusing a vial with a dose, correct?

A: Well, I don’t know if they’re confused, but they’re equating a vial with a dose. The cost of a vial with the cost of a dose.

Q: And this is the argument that Dr. Melgen and his team had been making all along the way through the ZPIC to the MAC to the Administrative Law Judge, the ALJ, to the other MAC, the Medicare Pills [*sic*] Counsel [*sic*], in which he lost at every step of the way, correct?

A: Correct.

(Sheehy 5/7/14 Tr. at 35.)

The government could have called witnesses from HHS, or presented the actual CDC or FDA guidance, or summarized the statutes, or summarized the case law. Instead the prosecution elected to instruct the grand jury with false testimony from its lead FBI case agent. Such false testimony was plainly used as an attempt to convince the grand jurors that Dr. Melgen was legally incorrect and that there was no confusion or policy issue.

VI. THE PROSECUTION IMPROPERLY COMMENTED ON THE EVIDENCE

The prosecution also did not heed the admonition that “a prosecutor may not make statements or argue in a manner calculated to inflame the grand jury unfairly against an accused.” Hogan, 712 F.2d at 759 (2d Cir. 1983) (citing Serubo, 604 F.2d at 1818). At times the prosecutors were unable to contain their desire to give inflammatory speeches to the grand jury. After eliciting testimony from Agent Sheehy about Dr. Melgen failing to prevail in his administrative appeal, Mr. Koski practiced his “one champion” speech – once again testifying like a ventriloquist through his case agent:

Q. So on the merits here, although Dr. Melgen has had many bites at the apple, he has lost every step of the way, correct?

A. Correct.

Q. But throughout his efforts, he has had one champion, correct?

A. Yes.

Q. Who has that champion been?

A. Senator Robert Menendez.

Q. The same Robert Menendez who got to fly on Dr. Melgen’s private jet, stay at his villa in the Dominican Republic, use his AmEx points for the hotel in Paris, got \$40,000 to his legal defense fund, same Senator Menendez, correct?

A. Same senator, yes.

(Sheehy 5/7/14 Tr. at 24-25.) This “exchange” was not really an “exchange” of questions and answers; it was not testimony at all – it was a closing argument, not appropriate for fact-finding by a supposedly independent grand jury. Not only was this “testimony” inflammatory, certainly the legal team that actually had championed Dr. Melgen’s cause all these years (among others) would take issue with the accuracy of Mr. Koski’s claim that Senator Menendez had been his “one champion.”

This sort of prosecutorial behavior is similar to Samango, a case in which the Ninth Circuit affirmed the dismissal of an indictment because the grand jury heard “much testimony by the prosecutor in the form of questions which . . . definitely conveyed the prosecutor’s belief that [the accused] was guilty.” 607 F.2d at 883. Mr. Koski similarly conveyed his personal belief in Defendants’ guilt in this case. This case is also similar to Breslin, where the court dismissed the indictment after finding “the prosecutor improperly characterized the evidence and inserted his opinions regarding the strength and weight of the evidence.” 916 F. Supp. at 443.

Beyond these sorts of remarks, the presentation to the jury was not focused on substantive crimes, but on presenting facts that would inflame the jury. For a case about purported political corruption, where the prosecution claims witnesses would include at least four U.S. Senators, a Cabinet Secretary, and scores of Executive Branch officials from numerous agencies, it is surprising that none were called before the grand jury. It is telling where the prosecution instead chose to focus its attention. The intended prejudice is obvious. The prosecution called every woman it could find who could provide irrelevant and prejudicial testimony concerning their alleged relationships with Dr. Melgen. (See, e.g., Sheehy Tr. of 2/26/14; 4/9/14 & 4/30/14 (reading back the testimony of various female acquaintances.). The grand jury also had to hear immaterial and prejudicial testimony from numerous pilots about

supposedly luxurious private planes (Sheehy Tr. of 2/26/14 at 37 (read-back of Butt testimony)), and from numerous guests who visited the Melgens in Casa de Campo about how supposedly luxurious their home was.¹⁹ Yet for all the time the prosecution had to bring in alleged

¹⁹ Every witness who had been to Casa de Campo was questioned extensively about how luxurious it was. Here is one such exchange between Ms. Abrishami and Agent Sheehy:

Q. Is Casa de Campo a luxury golf and sporting resort located in La Romana?

A. Yes.

Q. And La Romana is on the Caribbean coast of the Dominican Republic?

A. Correct.

Q. Does Casa de Campo have a marina?

A. Yes, it does.

Q. Three golf courses?

A. Yes.

Q. With 90 holes of golf?

A. Correct.

Q. Thirteen tennis courts?

A. Yes.

Q. Three polo playing fields?

A. Yes.

Q. Equestrian facilities?

A. Yes, it does.

Q. A 24-acre shooting facility?

A. Yes.

Q. A spa?

A. Yes.

Q. Beaches?

A. Yes.

Q. Restaurants?

A. Yes.

Q. And a hotel?

girlfriends, friends or relatives of alleged girlfriends, pilots and others to testify about things not particularly relevant or in dispute, the government could not find the time or space to call a single Executive Branch witness to a case alleging improper influence on those Executive Branch officials.

Anyone concerned with issues of fairness and justice would know that it is more important for a grand jury to hear from witnesses to purported acts of corruption to determine whether there in fact was corruption than for the grand jury to sit through extensive testimony to learn that Senator Menendez's close friend, Dr. Melgen, was wealthy and lived very comfortably. On the issues that mattered, the actual statements of the real Executive Branch witnesses did not support the prosecution's preferred version of what happened, so the grand jury was not allowed to hear from them. The conclusion is inescapable that the prosecution presented so much irrelevant testimony in their place because they either intended to inflame the grand jury and prejudice the jurors against the Defendants, or they were indifferent about inflaming and prejudicing the grand jury. Alone and, especially when viewed cumulatively, these actions requires dismissal.

A. It does.

Q. I'm going to show you now what's been marked -- oh, apologies. It was a 245-acre shooting facility. Correct?

A. Yes, that's correct.

Q. Not a 24-acre? I'm sorry. We got --

A. My mistake.

Q. So, a 245-acre shooting facility?

A. Yes.

(Sheehy 3/11/15 Tr. at 6-7.)

CONCLUSION

This case demonstrates how the prosecutor's manipulation of the grand jury eviscerated the purpose it was intended to serve: protection from unwarranted prosecutions. Accordingly, this case must be dismissed.

Respectfully submitted,

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